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September 10, 2002

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Request for Comment on First Amendment Issues
Docket No. 02N-0209

Dear Sir or Madam:

Enclosed please find two original sets of Comments of The Media Institute in response to the above-captioned Request for Comment. Please enter these Comments as part of the record in this proceeding. You may contact me at the above numbers, or directly at kaplar@mediainstitute.org, if you have any questions. Thank you.

Sincerely,

Richard T. Kaplar
Vice President

02N-0209

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Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD 20852

Request for Comment on First Amendment Issues	))))	Docket No. 02N-0209

COMMENTS OF THE MEDIA INSTITUTE

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I. INTRODUCTION

The Media Institute (the Institute) is a nonprofit research foundation specializing in communications policy and First Amendment issues. The Institute has long advocated a robust First Amendment and strong constitutional safeguards for those engaged in speech, including commercial speech. For more than a decade, the Institute has paid particular attention to government regulation of pharmaceutical industry speech and has expressed its concerns through court briefs, agency comments, and publications. The Media Institute submits these Comments in response to the Food and Drug Administration's Request for Comment on First Amendment Issues.[1] These comments will address FDA policies and practices that have been found to violate the First Amendment; the regulatory climate that led to this pattern of abuse; court actions that clarified the agency's obligations vis-à-vis the First Amendment; and recommendations for continued First Amendment compliance. The Institute applauds the FDA for taking the initiative, via this Request, "to ensure that its regulations, guidances, policies, and practices continue to comply with the governing First Amendment case law."[2]

II. BACKGROUND: REGULATORY POLICY GONE AWRY

The First Amendment provides no exemption to allow the regulation of speech about pharmaceutical products.[3] Nonetheless, the FDA acted for years as if such speech

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[1] *Request for Comment on First Amendment Issues, FDA Docket No. 02N-0209,* 67 Fed. Reg. 34942 (May 16, 2002) ("Request").

[2] *Id.*

[3] The First Amendment states: "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the

were indeed outside the ambit of First Amendment scrutiny. This stance was the result of three factors: (1) the FDA's assertion that speech about pharmaceutical products was a "special case" apart from other types of speech; (2) the unusual arrangement by which the FDA regulates not only pharmaceutical products, but also the speech of pharmaceutical companies about those products; and (3) the FDA's expansive definition of "promotional activity" to include the regulation of virtually all speech involved in drug labeling, advertising, and marketing. We shall consider these factors in turn.

A. The "Unique Nature" of Pharmaceutical Speech. Prescription drugs are differentiated from most other consumer products by the fact that the information accompanying the drug is so important. Such information is undeniably vital for the safe and efficacious use of the product. No rational person, after all, would risk swallowing an unmarked pill, not knowing what it was supposed to do, its strength, or possible side effects. This concept of information was articulated by an FDA deputy commissioner for policy:

> It is, after all, only within a particular information context that a drug really exists. Without all of the information on indications, dosage, and proper use contained in the labeling, coupled with the information and knowledge physicians possess about the use of drugs from their training and experience, a drug is not, in any practical sense, a drug. It's just a useless and probably dangerous chemical. But with the right information, a drug can be a therapeutic tool of enormous and often lifesaving value to patients.[4]

In this sense information is part of the product, an element of the drug's essential nature. As economist John Calfee has noted:

> The main difference between a chemical entity and a marketable drug is information about what the chemical does under various conditions. Information is therefore the linchpin of pharmaceutical markets. The same is true of the market for medical devices, where precise information on how to use a surgical pin, for example, may be the most essential aspect of the product.[5]

This equation -- chemical + information = drug -- explains the "unique" status of pharmaceutical speech. It follows that if the FDA is charged with regulating a prescription drug, it must necessarily regulate the information immediately surrounding that drug since

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people peaceably to assemble, and to petition the Government for a redress of grievances." U.S. Const. amend. I.

[4] Michael R. Taylor, "Drug regulation, off-label uses, and CME -- Reconciling competing values," speech to Food and Drug Law Institute, Feb. 26, 1992, at 3-4.

the information is as much a part of the drug as is the chemical substance. This is a defensible position. However, the FDA has historically taken this one step further to assert that since the intertwining of drug product and information is unique, the information is thereby transformed into something so different from other speech that it falls outside the protection of the First Amendment. This position is not defensible, as we shall discuss later.

B. The FDA's Dual Authority. The FDA is unusual in that it possesses regulatory control over both a product itself and the advertising for that product. Advertising for most products falls under the jurisdiction of the Federal Trade Commission (FTC), as did prescription drug advertising prior to 1962. But with passage of the 1962 Drug Amendments,[6] the FDA gained statutory authority over drug advertising in addition to labeling, which it had controlled since passage of the Food, Drug, and Cosmetic Act of 1938.[7] Thus the FDA is in the enviable position (from a regulator's point of view) of being able to allow the introduction of certain new products into the marketplace and bar the introduction of others; specify ways in which the product should be used; control the dissemination of information about the product through labeling (as broadly defined); and control what the manufacturer may say about the product in advertising.

In addition, the FDA has been aggressive in asserting its authority as new situations have arisen. When drug companies began to expand their use of video news releases, press conferences, symposia, and other means of communication in the 1980s and '90s, for example, the FDA asserted regulatory authority over such techniques. As then-FDA Commissioner David Kessler famously stated in a 1990 article: "How expansive the FDA's reach is remains an unsettled question.... Until further judicial decisions or congressional action clarifies the FDA's specific authority in the area of promotion, the FDA will continue to assert broad jurisdiction."[8] In other words, we're going to keep doing it until someone tells us we can't. Seven years would pass before the courts finally spoke.

Unfortunately, the "dual authority" scheme at the FDA led to a breakdown in the traditional system of checks on excesses of power. This is especially troubling because speech is involved. Because new drugs cannot be marketed until they have been approved by the FDA, drug makers are beholden to the agency for their economic well being. This makes companies unwilling to antagonize the agency over questions of advertising and la-

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[5] John E. Calfee, "Free speech, FDA regulation, and market effects on the pharmaceutical industry," in Richard T. Kaplar, ed., *Bad Prescription for the First Amendment* (The Media Institute, 1993), at 64.
[6] Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified at 21 U.S.C. Sec. 502 (n)).
[7] 21 U.S.C. Sec. 301 *et seq.* (1997).
[8] David A. Kessler and Wayne L. Pines, "The federal regulation of prescription drug advertising and promotion," 264 *JAMA* 2409, 2411 (1990).

beling lest the FDA slow the approval process for a company's new drugs. Companies are understandably reluctant to stand up in court for their free speech rights when faced with such overwhelming economic consequences. As a result, few if any companies challenge the FDA in court when the agency rejects ads proposed as part of new-drug "launch" materials or objects to ads for existing products. As Commissioner Kessler observed in the same article: "Companies interested in maintaining positive relationships with the FDA usually agree to the FDA's remedy."[9] And staying on good terms does not include taking the FDA to court. Ultimately it was a nonprofit legal foundation -- not a pharmaceutical manufacturer -- that mounted a successful First Amendment court challenge to the FDA's policies and practices.[10]

C. The FDA's Expansive Definition of "Promotional Activity." A key term in FDA parlance is "promotional activity," because it describes a range of drug company activity that the agency can regulate. The FDA defines promotional activities quite expansively to include virtually all product information disseminated or sponsored by a drug maker. Both labeling and advertising are promotional activities in the FDA's view.

Congress defined labeling in the Food, Drug, and Cosmetic Act as any written, printed, or graphic matter upon or accompanying a drug.[11] Most people would correctly assume that this includes the package label and "package insert," the sheet of fine print that contains extensive product information on indications, dosage, side effects, etc.

In its implementing regulations, however, the FDA defined labeling as something far broader and more akin to marketing. The FDA considered labeling to include:

> Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, lantern slides, sound recordings, exhibits, literature, and reprints of similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, in the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor.[12]

FDA regulations defined advertising in an encompassing manner:

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[9] *Id.* at 2410.

[10] *Washington Legal Foundation v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998); *Washington Legal Foundation v. Friedman,* 56 F. Supp. 2d 81 (D.D.C. 1999).

[11] 21 U.S.C. Sec. 321 (k), (m).

[12] 21 C.F.R. 202.1 (1)(2).

> [A]dvertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communications systems.[13]

These sweeping definitions gave the FDA regulatory authority over virtually all drug company speech about pharmaceutical products. From a constitutional standpoint, however, matters were made far worse because the FDA believed it could regulate this broad range of speech without regard for the First Amendment rights of the speakers.

III. FDA PRACTICES WENT UNCHECKED BY THE ADMINISTRATIVE PROCEDURE ACT AND THE FIRST AMENDMENT

The FDA's regulatory adventurism reached its zenith in the 1990s during the tenure of Commissioner Kessler. In October 1991, the FDA released a "draft concept paper"[14] intended to articulate the agency's policy regarding the growing practice of industry-sponsored seminars (continuing medical education or CME), primarily on the off-label uses of prescription drugs. The paper sought to "describe a category of educational activities that may continue to be funded by drug companies and yet avoid regulation as advertising or promotional labeling."[15] The distinction turned on whether a drug company influenced the content of an educational program. A drug company could fund a scientific and educational program presented by a third party without triggering FDA regulation if the drug company did not "exert control, express or implied, over the scientific content."[16] The draft concept paper listed 21 measures of independence and scientific rigor with which a drug company would have to comply to avoid regulation. The draft concept paper sparked a strong response from industry and, after revisions, was released in 1992 as a "draft policy statement." After an extended period of comment and revision, the document was released as "final guidance" in December 1997.[17]

Concurrently, the FDA addressed the topic of "enduring materials," or reprints of textbook and journal articles -- again, primarily those describing off-label uses of prescription drugs. The agency released final guidance in October 1996.[18] This guidance likewise established criteria about the independence and objectivity of the publication and the article content in instances where drug manufacturers wished to initiate distribution to physicians

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[13] 21 C.F.R. 202.1 (1)(1).
[14] FDA, "Drug company supported activities in scientific or educational contexts: Draft concept paper," Oct. 26, 1991.
[15] *Id.* at 1.
[16] *Id.* at 6.
[17] 62 Fed. Reg. 64074 (1997).
[18] 61 Fed. Reg. 52800 (1996).

or others. The guidance required that the article deal principally with approved uses of a drug, and restricted drug company distribution of articles about off-label uses. Textbook excerpts and journal articles that failed to meet this guidance would be considered promotional and subject to regulation -- unless a drug maker was responding to a physician's request for the materials.

In November 1997, the Food and Drug Administration Modernization Act of 1997 (FDAMA) became law.[19] This act modified the "enduring materials" guidance to allow drug company distribution of reprints about off-label uses, but with a major catch: A drug maker would have to submit an application to have the off-label use approved by the FDA, or certify that it would submit such an application within six months of distributing the reprint.[20] The act did not address CME programs.

A. Regulating Without Regulations. The draft concept paper and draft policy statement were two of the FDA's most visible -- and most flagrant -- attempts to regulate the speech of pharmaceutical companies without conducting formal rulemaking proceedings. The FDA expected drug companies to comply with these documents even though they were only "drafts," and despite the fact that discussions, the submission of written comments, and revisions were ongoing. In any other agency this would be an unthinkable practice -- akin to enforcing a proposed rule as soon as it was first published, prior to the receipt and review of comments from interested parties or the adoption of a final regulation.

And yet the draft papers were hardly the only examples of the FDA's practice of regulating without regulations. In 1991, for example, the agency tried to regulate public relations materials and video news releases (VNRs) by sending letters to drug makers.[21] The letters said that the companies should send public relations materials and VNRs to the FDA as samples of promotional labeling and advertising at the time of initial distribution. VNRs were to be submitted for review if they mentioned a drug use at all, even if they did not mention a drug or drug company by name.

Another major issue, direct-to-consumer prescription drug advertising, gained the FDA's attention in the 1980s when drug companies began directing ads to consumers in addition to their traditional audience of doctors. In a policy statement released in September

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[19] Pub. L. No. 105-115, 111 Stat. 2296 (1997).

[20] *Id.* at Sec. 551 (b).

[21] Letter from Carl C. Peck, M.D., director, Center for Drug Evaluation and Research, FDA, to drug manufacturers, July 24, 1991.

1983, the agency asked for a "voluntary moratorium on this practice."[22] Thus the FDA in effect directed the pharmaceutical industry, without warning, to stop promoting prescription drugs to consumers. The agency did this without following the notice and comment requirements of the Administrative Procedure Act and its own regulatory statute, 21 U.S.C. Sec. 371(e). Two years later, however, the FDA lifted the moratorium by publishing a notice in the Federal Register[23] -- again without going through the rulemaking process.

In July 1993, the FDA began requesting "that drug manufacturers voluntarily submit proposed direct-to-consumer promotional material prior to use, allowing FDA the opportunity to review and comment upon proposed materials before they reach consumers."[24] Drug companies treated this non-binding "request" as an edict, however, subjecting virtually all such promotional material to the FDA's prior restraint. Moreover, in 1995 the agency acknowledged that it was applying "prescription drug advertising regulations to both professional and consumer-directed promotion on a case-by-case basis."[25] This arbitrary and perhaps even whimsical practice was made more novel still, owing to the fact that, by the agency's own admission, there were no regulations in effect at the time that applied specifically to consumer-directed promotional materials.[26]

Many other examples could be cited, but suffice it to say that, for at least the past two decades, the FDA carried out an extensive program of regulation through draft documents, letters to drug companies, press releases, speeches, "requests" for "voluntary" action, and other means well outside the bounds of the rulemaking procedures set forth in the Administrative Procedure Act. Fearing retribution for non-compliance in the form of delayed drug approvals, drug manufacturers meekly complied.

B. Regulating Without the First Amendment. Not only has much of the FDA's regulatory agenda been carried out without benefit of formal regulations, but virtually all of it -- at least until quite recently -- has been carried out without regard for the First Amend-

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[22] FDA policy statement, "Direct-to-consumer advertising of prescription drugs, moratorium," Sept. 2, 1983, *cited in Direct-to-Consumer Promotion of Prescription Drugs, Notice of Public Hearing, FDA Docket No. 95N-0227,* Aug. 7, 1995 ("1995 Notice"), at 3.

[23] 56 Fed. Reg. 36677 (1985).

[24] 1995 Notice, *supra* note 22, at 4. The FDA subsequently backed off from this position, at least officially. *See* 61 Fed. Reg. 34214 (1996). Nonetheless, drug makers knew that FDA staff remained very tough on ads that had not been "precleared."

[25] *Id.* at 3.

[26] *Id.* In this Notice the FDA candidly conceded: "Rigorous studies are needed to assess the actual effects of direct-to-consumer promotion and to help guide future policy." *Id.* at 4. In other words, the FDA had no rules in effect to regulate DTC promotional materials, and no empirical basis for implementing a regulatory scheme -- yet sought to control drug makers' DTC materials anyway.

ment. As we noted earlier, the agency adopted the stance that information about drugs is so critical, and so intertwined with the product, that it must be subject to total and unfettered government control.

This bureaucratic arrogance reached new levels in the draft concept paper / draft statement / final guidance debacle over educational seminars and enduring materials. Here the agency attempted to extend its regulatory grasp not only to the speech of drug manufacturers, but to the speech of third parties -- scientists, researchers, scholars -- engaged in scientific and educational discourse. The Media Institute has long contended that this type of speech is the very essence of "core speech" fully protected by the First Amendment.[27]

The FDA, however, disagreed. It asserted, for instance, that it could prevent an independent researcher from discussing certain uses of a drug at a seminar for physicians, and that it could prohibit a drug company from distributing reprints of an article written by an independent scientist and published in a peer-reviewed academic journal. Such scholarly speech was reduced to the level of promotional hyperbole, the FDA claimed, if its dissemination was facilitated by a drug manufacturer.[28] (Once again, drug makers had little room for complaint since the fear of economic retribution hung heavily over their heads.)

In the landmark case brought by the Washington Legal Foundation (WLF), the FDA argued that its guidance documents were beyond First Amendment scrutiny because they were a restraint upon conduct rather than speech.[29] The court found this argument "somewhat difficult to discern" and dismissed it quickly.[30] The court agreed with the plaintiff's counsel that "the activities at issue in this case are only 'conduct' to the extent that moving one's lips is 'conduct,' or to the extent that affixing a stamp and distributing information through the mails is 'conduct.'"[31]

The FDA next asserted that its guidance documents were not subject to constitutional challenge "because of the federal government's extensive power to regulate the pharmaceutical industry through the Pure Food and Drug Act, 21 U.S.C. Sec. 331 *et seq.*"[32] Claiming that it was "well within its statutory authority," the FDA cited other types of regulated communications, including "information about securities, corporate proxy statements, the exchange of price and production information among competitors in antitrust regulation, and employer's threats of retaliation for the labor activities of employ-

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[27] *See, e.g.*, Richard T. Kaplar, ed., *Bad Prescription for the First Amendment* (The Media Institute, 1993).
[28] *See* FDA final guidance documents, *supra* notes 17, 18.
[29] *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 59 (D.D.C. 1998).
[30] *Id.*
[31] *Id.*
[32] *Id.* at 60.

ees."[33] The FDA also cited two other court decisions for the proposition that certain types of speech can be regulated without offending the First Amendment.[34] However, the court found these arguments unpersuasive, as we shall discuss below.

IV. COURTS HAVE MADE CLEAR THAT THE FDA IS SUBJECT TO THE FIRST AMENDMENT

In both the Washington Legal Foundation challenge and in other cases, federal courts from the district level to the U.S. Supreme Court have ruled unequivocally that FDA regulations fall under First Amendment scrutiny.

A. FDA Rules Are Not Exempt Even if They Are Part of a Broad Regulatory Scheme. In the WLF case, the district court did not agree with the FDA that speech about pharmaceutical products constituted "a distinct category of communications" subject to strict regulation and thus outside First Amendment review. "[T]he argument that a certain subset of speech may be considered completely outside of the First Amendment framework because the speech occurs in an area of extensive government regulation is a proposition whose continuing validity is at best questionable in light of the Supreme Court's most recent commercial speech cases," the court said.[35]

The court noted that since the Supreme Court's ruling in *Central Hudson Gas & Electric Corp. v. Public Service Commission*,[36] "the Supreme Court has consistently applied a speech analysis -- whether under the pure speech or commercial speech framework -- to cases involving statutes and/or regulations in areas subject to extensive state or federal regulation."[37] The district court also noted the Supreme Court's ruling in *44 Liquormart, Inc. v. Rhode Island*, in which the High Court repudiated its earlier teaching in *Posadas* --

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[33] *Id., citing* Defendants' Reply Memorandum at 8, *quoting Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978).

[34] *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 759 n.5 (1985); *Securities & Exchange Commission v. Wall Street Publishing Institute, Inc.*, 851 F.2d 365, 373 (D.C. Cir. 1988). *Dun & Bradstreet* dealt with the regulation of business information, in this case an erroneous credit report. *Wall Street Publishing* dealt with the regulation of a magazine covering the stock market.

[35] *Washington Legal Foundation*, 13 F. Supp. 2d at 60.

[36] *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980).

[37] *Washington Legal Foundation*, 13 F. Supp. 2d at 60, *citing Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (alcohol labeling); *Turner Broadcasting System, Inc. v. FCC*, 512 U.S. 622 (1994) (telecommunications); *Pacific Gas and Electric Co. v. Public Utilities Commission of California*, 475 U.S. 1 (1986) (utilities); *Friedman v. Rogers*, 440 U.S. 1 (1979) (optometry); and *Florida Bar v. Went for It, Inc.*, 515 U.S. 618, 635 (1995) (attorney conduct).

that government could regulate speech without implicating the First Amendment provided it had the power to regulate the underlying activity.[38]

The district court in *Washington Legal Foundation* then went on to find that the speech at CME seminars and in book excerpts and article reprints was commercial speech if a drug company used it for promotional purposes. It was only this promotional use that caused third-party speech to merit a lesser degree of First Amendment protection, for as the court made clear:

> It is beyond dispute that when considered outside of the context of manufacturer promotion of their drug products, CME seminars, peer-reviewed medical journal articles and commercially-available medical textbooks merit the highest degree of constitutional protection. Scientific and academic speech reside at the core of the First Amendment.[39]

However, the CME and enduring materials at issue were still "entitled to the qualified but nonetheless substantial protection accorded to commercial speech," the court said.[40]

B. FDA Restrictions Challenged by WLF Failed the *Central Hudson* Test. The district court then analyzed the FDA's guidance documents on CME and enduring materials according to the four-part *Central Hudson* test. Under this test, restrictions on commercial speech are constitutional if (1) the speech concerns a lawful activity and is not misleading; (2) the government has a substantial interest that would be furthered by the restrictions; (3) the restrictions advance the government's substantial interest in a direct and material way; and (4) the regulations are no more restrictive of speech than necessary.[41] The court found the regulations at issue unconstitutional because they failed the fourth prong of the *Central Hudson* test. "[T]he restrictions in the Guidance Documents are considerably more extensive than necessary to further the substantial government interest in encouraging manufacturers to get new uses on-label," the court concluded.[42]

C. The Supreme Court Recently Ruled That Statutory Provisions Restricting Drug-Related Speech Were Unconstitutional. In *Thompson v. Western States Medical Center*, the Supreme Court in April 2002 upheld a ruling by the U.S. Court of Appeals for the Ninth Circuit that struck down a portion of the Food and Drug Administration Moderniza-

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[38] *Washington Legal Foundation*, 13 F. Supp. 2d at 61, *citing 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); and *Posadas de Puerto Rico Assoc. v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986).
[39] *Washington Legal Foundation*, 13 F. Supp. 2d at 62.
[40] *Id.* at 65, *quoting Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 68 (1983).
[41] *Central Hudson Gas & Electric Corp.*, 447 U.S. at 566.
[42] *Washington Legal Foundation*, 13 F. Supp. 2d at 73.

tion Act of 1997 (FDAMA).[43] Subsections of the act prohibited pharmacists from advertising and promoting the fact that they created "compounded" drugs by mixing ingredients for individual patients. The Court treated the pharmacists' advertising as commercial speech and applied the *Central Hudson* test. The Court found the statute more restrictive than necessary in furthering the government's substantial interest of maintaining the integrity of the FDA's approval process for new drugs.[44]

The *Central Hudson* test came into play in yet another recent case involving the FDA. In *Pearson v. Shalala*,[45] the U.S. District Court for the District of Columbia ruled in 2001 that the FDA violated the commercial speech rights of dietary supplement manufacturers and sellers seeking FDA approval for a folic acid health claim. The court found that the FDA's refusal to allow the health claim, or to specify language for a disclaimer, violated the First Amendment. In particular, the FDA violated the fourth prong of *Central Hudson* by employing a method (*i.e.*, total suppression of speech) that was more restrictive than necessary.[46] Other courts over the years have found FDA-regulated speech to be commercial speech, and have used the *Central Hudson* test to assess the constitutionality of the FDA's restrictions.[47] Whether the speech restrictions have been ultimately upheld or struck down, the important point is that the courts have regarded the speech in question as commercial speech, falling well within the ambit of the First Amendment and meriting significant constitutional protection.

V. CONCLUSION: THE FDA'S NEW-FOUND AWARENESS OF THE FIRST AMENDMENT SHOULD GUIDE ITS ACTIONS IN THE FUTURE

There can be no argument that for many years the FDA acted with brazen impunity with regard to the First Amendment rights of pharmaceutical makers. With a broad mandate to regulate both drug products and virtually all speech by drug makers about those products, the agency found ways to impose its ever-expanding grip on the industry. It did this through extra-regulatory means such as "draft" policy papers, "requests" to drug companies, jawboning, and other techniques that yielded industry compliance without bother-

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[43] *Thompson v. Western States Medical Center*, 122 S. Ct. 1497 (2002).
[44] *Id.* at 1506-07.
[45] *Pearson v. Shalala*, 130 F. Supp. 2d 105 (D.D.C. 2001).
[46] *Id.* at 120.
[47] *Washington Legal Foundation*, 13 F. Supp. 2d at 61-62, *citing Nutritional Health Alliance v. Shalala*, 953 F. Supp. 526 (S.D.N.Y. 1997); *Pearson v. Shalala*, 1998 WL 440621 (D.D.C. Jan. 12, 1998); *National Council for Improved Health v. Shalala*, 893 F. Supp. 1512, 1516-17 (D. Utah 1995); *United States v. General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986); *Federal Trade Commission v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35 (D.C. Cir. 1985); and *Association of National Advertisers, Inc. v. Lungren*, 44 F.3d 726, 728-29 (9th Cir. 1994).

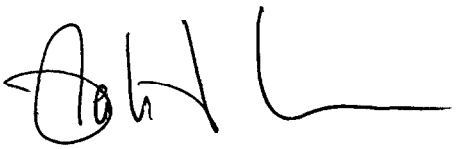
ing with the Administrative Procedure Act or statutory provisions for rulemaking. Drug companies, fearing the FDA would retaliate by holding up new-drug approvals, were forced to relinquish their constitutional rights rather than jeopardize their business interests by challenging the FDA's practices.

However, a string of court decisions in recent years, capped by the remarkable Washington Legal Foundation case, has captured the agency's attention and forced it to recognize that the FDA is indeed subject to the First Amendment. Drug makers' speech about their products -- while critical to the safe and efficacious use of those products -- is not a unique category of expression beyond the reach of the First Amendment -- it is, by and large, commercial speech that merits significant (if not absolute) First Amendment protection. We are heartened to see that the FDA has now gone so far as to seek comment on how well it is meeting its First Amendment obligations.

Toward this end, The Media Institute offers a number of simple recommendations: (1) Heed the courts (including the Supreme Court) and henceforth scrutinize all potential regulations that would restrict drug makers' speech about their products according to the *Central Hudson* test. (2) Regulate the industry only through bona fide rulemaking proceedings carried out in compliance with the Administrative Procedure Act and statutory requirements. Regulation through intimidation, using extra-legal "informal" or "voluntary" tactics, must become a thing of the past. (3) Make an affirmative policy determination to operate within the bounds of the First Amendment in all proceedings, rather than asserting unlimited authority until challenged. (4) Be mindful that the lack of court challenge does not necessarily imply FDA compliance with the First Amendment. A more robust First Amendment interplay between regulator and regulated will likely not occur as long as the FDA possesses the authority to regulate both the product itself and the manufacturer's speech about the product. (5) Take affirmative steps to dispel the perception that drug companies are punished (in the form of delayed approvals) for exercising their First Amendment right to challenge FDA restrictions on their speech. This implies, of course, that the FDA will refrain from actually engaging in such retribution.

The present leadership of the FDA has an unparalleled opportunity -- nay obligation -- to undertake a systemic "clean up" of FDA regulatory practices that have been long on intimidation and short on constitutional safeguards. A return to established rulemaking procedures, coupled with a heightened awareness of First Amendment concerns, should yield far-reaching benefits to the agency, the industry, and consumers alike.

Respectfully submitted,



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